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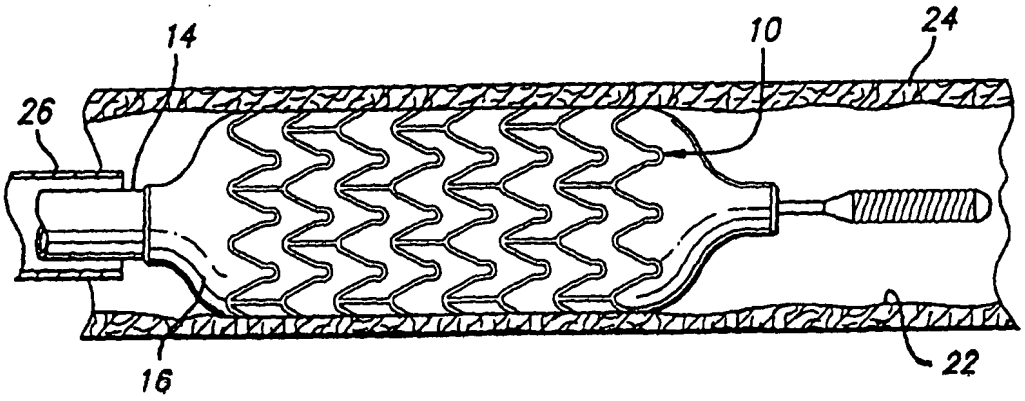

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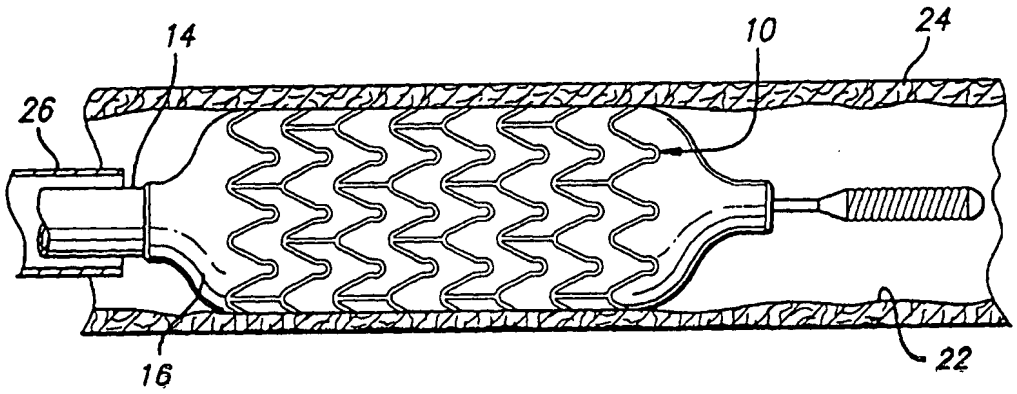

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WO 02/05863 A1

RADIOPAQUE STENT COMPOSED OF A BINARY ALLOY

BACKGROUND OF THE INVENTION

The present invention relates generally to endoprosthesis devices, which are commonly referred to as stents, and more particularly to radiopaque stents.

Stents are generally thin walled tubular-shaped devices composed of complex patterns of interconnecting struts which function to hold open a segment of a blood vessel or other body lumen such as a coronary artery. They also are suitable for supporting a dissected arterial lining or intimal flap that can occlude a vessel lumen. At present, there are numerous commercial stents being marketed throughout the world. These devices are typically implanted by use of a catheter which is inserted at an easily accessible location and then advanced through the vasculature to the deployment site. The stent is initially maintained in a radially compressed or collapsed state to enable it to be maneuvered through the lumen. Once in position, the stent is deployed. In the case of self-expanding stents, deployment is achieved by the removal of a restraint, such as the retraction of a delivery sheath. In the case of balloon expandable stents, deployment is achieved by inflation of a dilation balloon about which the stent is carried on a stent-delivery catheter.

The stent must be able to simultaneously satisfy a number of mechanical requirements. First, the stent must be capable of withstanding the structural loads, namely radial compressive forces, imposed on the stent as it supports the walls of a vessel lumen. In addition to having adequate radial strength or more accurately, hoop strength, the stent should be longitudinally flexible to allow it to be maneuvered through a tortuous vascular path and to enable it to conform to a deployment site that may not be linear or may be subject to flexure. The material from which the stent is constructed must allow the stent to undergo expansion which typically requires substantial deformation of localized portions of the stent's structure. Once expanded, the stent must maintain its size and shape throughout its service life despite the various forces that may come to bear thereon, including the cyclic loading induced by the

beating heart. Finally, the stent must be biocompatible so as not to trigger any adverse vascular responses.

In addition to meeting the mechanical requirements described above, a stent should also be radiopaque or fluoroscopically visible. Accurate stent placement requires real time visualization to allow the vascular surgeon to track the delivery catheter through the patient's vasculature and precisely place the stent at the site of a lesion. This is typically accomplished by fluoroscopy or similar x-ray visualization procedures. For a stent to be fluoroscopically visible it must be more absorptive of x-rays than the surrounding tissue. This is typically accomplished by the use of radiopaque materials in the construction of a stent, which allows for its direct visualization. The most common materials used to fabricate stents are stainless steel and nickel-titanium alloys, neither of which is particularly radiopaque. This factor, in combination with the relatively thin wall thickness (about 0.002 to 0.006 inch) of most stent patterns renders stents produced from these materials insufficiently radiopaque to be adequately visualized with fluoroscopy procedures. Although both materials are generally regarded as being bio-compatible, some recent concerns have arisen regarding the biocompatibility of stainless steel. Over time, nickel, a constituent element of most stainless steels, tends to leach from a stainless steel stent and in some sensitive patients will produce an allergic reaction. In addition, the chromium oxide layer present on the surface of stainless steel stents to prevent corrosion may have a tendency to degrade during long term use within the body.

Alternative, non-toxic, high density metals, such as tantalum, iridium, platinum, gold, and the like, have been used in prior art stents. However, these alloys are either excessively radiopaque or may lack sufficient strength for recoil, radial strength requirements, and long-term use in a dynamic vascular setting. Stents constructed of highly radiopaque materials appear overly bright when viewed under a fluoroscope. This tends to overwhelm the image of the tissue surrounding the stent and obscures visualization of the stent lumen. Due to the lack of an appropriately radiopaque material, simply constructing a stent wholly out of a single material has

heretofore not resulted in a stent with the optimal combination of mechanical properties and radiopacity. Thus, the art has moved in the direction of combining different materials to produce a mechanically sound, biocompatible and fluoroscopically visible stent. A number of such approaches have been developed. Typically such methods have focused on increasing the radiopacity or fluoroscopic visibility of stainless steel and nickel-titanium alloy stents.

One means frequently described for increasing fluoroscopic visibility is the physical attachment of radiopaque markers to the stent. Conventional radiopaque markers, however, have a number of limitations. Upon attachment to a stent, such markers may project from the surface of the stent, thereby comprising a departure from the ideal profile of the stent. Depending on their specific location, the marker may either project inwardly to disrupt blood flow or outwardly to traumatize the walls of the blood vessel. Additionally, galvanic corrosion may result from the contact of two disparate metals, i.e., the metal used in the construction of the stent and the radiopaque metal of the marker. Such corrosion could eventually cause the marker to separate from the stent which may be problematic should the marker be swept downstream within a vessel. Discrete stent markers cannot show the entire outline of the stent which is a preferred method to determine the optimal expansion of a stent over its entire length.

The radiopacity of stents has also been increased by plating or coating selected portions thereof with radiopaque material. However, a number of disadvantages are associated with this approach as well. When the stent is expanded certain portions undergo substantial deformation, creating a risk that cracks may form in the plating or coating causing portions of the plating to separate from the underlying substrate. This has the potential for creating jagged edges that may inflict physical trauma on the lumen wall tissue or cause turbulence in the blood flowing past the stent, thereby inducing thrombogenesis. Moreover, once the underlying structural material becomes exposed to an electrolytic solution such as blood, interfaces between the two

disparate metals become subject to galvanic corrosion. Over time, galvanic corrosion may also lead to separation of the plated material from the underlying substrate.

As can be seen, composite stents, whether equipped with markers or radiopaque plating, have several disadvantages; namely, separation of the markers, plating, or coating from the substrate material, which may allow the metallic particles to flow downstream within a vessel lumen causing potential blockages or other adverse effects upon the patient.

What is needed therefore is a stent that overcomes the shortcomings inherent in previously known devices. Preferably, such a stent would be formed from a single material, possess the required mechanical characteristics, and also be sufficiently radiopaque to be readily visible using fluoroscopy procedures.

SUMMARY OF THE INVENTION

The present invention provides a stent made from a binary alloy of either tantalum-tungsten or tantalum-niobium that overcomes the shortcomings of previously known stent devices. The stent fulfills all of the mechanical and structural requirements attendant to its function as a stent. Moreover, in contrast to the prior art, the stent is sufficiently radiopaque to allow for good imaging of the stent under fluoroscopy without the addition of an extra layer of radiopaque material. In addition, the stent is not overly bright and therefore does not obscure the image of the surrounding vessel lumen into which the stent is placed, as would be the case with a stent made from pure tantalum.

The stent of the present invention achieves its results by utilizing the heretofore unappreciated properties of tantalum-tungsten and tantalum-niobium alloys. Tantalum-tungsten alloys have approximately the same radiopacity as pure tantalum, however, the alloys are substantially stronger than pure tantalum and in some compositions are also stronger than stainless steel. The alloy's strength allows for a stent to be produced with a wall thickness comparatively thinner than that of a stent produced from pure tantalum. Since radiopacity is function of material density, and of the stent's

wall or strut thickness, it is possible to tailor the thickness of tantalum-tungsten stents to produce a stent with a radiopacity less than that of a pure tantalum stent, yet greater than that of a conventional stainless steel stent.

Tantalum-niobium alloys with a high percentage of niobium (about 40%) are stronger than pure tantalum and, more importantly, are substantially less dense than pure tantalum as niobium has an atomic mass of approximately one half that of tantalum. Thus, the thickness of a tantalum-niobium alloy stent may also be tailored to achieve a radiopacity between that of a pure tantalum stent and a conventional stainless steel stent.

The stent of the present invention may have virtually any configuration that is compatible with, and maintains the patency of, the body lumen in which it is implanted. Typically, stents are composed of an intricate geometric pattern of cylindrical rings and connecting links. These interconnecting elements are commonly referred to as struts. Presently, there are a wide variety of strut patterns known in the art.

In one exemplary embodiment, the stent of the present invention includes generally a plurality of cylindrical rings that are interconnected by a plurality of links. Each of the cylindrical rings making up the stent have a proximal end and a distal end and a cylindrical plane defined by a cylindrical outer wall surface that extends circumferentially between the proximal end and the distal end of the cylindrical ring. The cylindrical rings typically comprise a plurality of alternating peaks and valleys, where the valleys of one cylindrical ring are circumferentially offset from the valleys of an adjacent cylindrical ring. In this configuration, the connecting links attach each cylindrical ring to an adjacent cylindrical ring so that the links are positioned substantially within one of the valleys and attach the valley to an adjacent peak. Generally, the cylindrical rings are interconnected by at least one connecting link between adjacent cylindrical rings and each connecting link may be circumferentially offset from the previous connecting link in a preceding ring.

While the cylindrical rings and connecting links generally are not separate structures, they have been conveniently referred to as rings and links for ease of identification. Further, the cylindrical rings can be thought of as comprising a series of

U's, W's and Y-shaped structures in a repeating pattern. Again, while the cylindrical rings are not divided up or segmented into U's, W's and Y's, the pattern formed by the rings resembles such a configuration. The U's, W's and Y's promote flexibility in the stent primarily by flexing and by tipping radially outwardly as the stent is delivered through a tortuous vessel.

The present invention stent not only is more visible under fluoroscopy, it also is more compatible for magnetic resonance imaging (MRI). Although the technique for viewing a stent by MRI is different than that under fluoroscopy, it is anticipated that the present invention stent will have more useful visibility under MRI in terms of being able to image near the stent and inside the stent lumen, during placement of the stent, and during follow-up procedures.

Preferably, the stent of the invention may be formed from a tube by laser cutting the pattern of cylindrical rings and connecting links in the tube. The stent also may be formed by laser cutting a flat metal sheet in the form of the rings and links, and then rolling the pattern into the shape of the cylindrical stent and providing a longitudinal weld to form the stent. Other methods of forming stents are well known and include chemically etching a flat metal sheet and rolling and then welding it to form the stent, or coiling a wire to form the stent. In addition, hoops or rings may be cut from tubing stock, the tube elements stamped to form crowns, and the crowns connected by welding or laser fusion to form the stent.

These and other features and advantages of the present invention will become apparent from the following detailed description, which when taken in conjunction with the accompanying drawings, illustrate by way of example the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view, partially in section, depicting a stent embodying features of the invention and which is mounted on a balloon dilatation catheter and disposed within an artery.

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 depicting the stent expanded within the artery, so that the stent embeds within the arterial wall.

FIG. 3 is an elevational view, partially in section, showing the expanded stent implanted in the artery wall after withdrawal of the balloon catheter.

FIG. 4 is a perspective view of a stent embodying features of the invention, shown in an unexpanded state.

FIG. 5 is a perspective view of a stent embodying features of the invention shown, in an expanded state.

FIG. 6 is a plan view of a flattened section of the stent of the invention illustrating the pattern of the stent shown in FIG. 4.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention stent improves on existing stents by utilizing the heretofore unappreciated properties of certain binary alloys of tantalum and in particular the properties of tantalum-tungsten and tantalum-niobium alloys. Stents produced from these alloys may have tailored wall or strut thicknesses such that the stents are sufficiently radiopaque to be readily visualized under fluoroscopy during a stent

placement procedure, yet are not so radiopaque as to interfere with the visualization of surrounding body tissue or stent lumen. In addition, since the stent is produced from a single material, the present invention stent overcomes the drawbacks associated with composite or plated stents, namely corrosion and separation of the radiopaque layer.

The stent of the present invention can have virtually any configuration that is compatible with the body lumen in which it is implanted. Typically stents are composed of an intricate geometric pattern of cylindrical rings and connecting links. These elements are commonly referred to as struts. Generally, the struts are arranged in patterns which are designed to contact the lumen walls of a vessel and to maintain patency of the vessel thereby. A myriad of strut patterns are known in the art for achieving particular design goals. A few of the more important design characteristics of stents are radial or hoop strength, expansion ratio or coverage area, and longitudinal flexibility. One strut pattern may be selected over another in an effort to optimize those parameters that are of importance for a particular application. An exemplary strut pattern will be described below.

A comparison of the relevant mechanical properties of tantalum-tungsten ("Ta-W") and tantalum-niobium ("Ta-Nb") alloys with respect to stainless steel type 316L and pure tantalum are compiled in Table 1. The type 300 series stainless steel is most commonly used in stent applications with type 316L generally being preferred.

Table 1

Material	Yield Strength (ksi)	Tensile Strength (ksi)	Elastic Modulus (msi)	Elongation %	Density (g/cm^3)
316L SS (annealed)	36,40	85	29	55	8.00
Tantalum (annealed)	25	40	26	50	16.6
Ta-2.5%W	35	55	26	40	16.6
Ta-10%W	70	90	30	30	16.9
Ta-40%Nb	30	45	22	40	12.1

There is a highly positive correlation between material density and radiopacity. Thus, the greater a material's density, the greater the material's radiopacity. For example, with reference to Table 1, for a given stent pattern with uniform thickness, a tantalum stent will be approximately twice as radiopaque as the same stent produced from stainless steel. There is also a generally linear relationship between material thickness and radiopacity. Thus for two stents of the same stent pattern and material, but having different strut thicknesses, the stent with the greater strut thickness will be proportionately more radiopaque.

The radial or hoop strength of a stent varies, generally, as a function of the strut thickness cubed (t^3). For this reason, stents utilizing identical stent patterns and being designed to have substantially the same radial strength may have comparatively large differences in strut thickness as result of apparently small differences in material yield strength.

The above description of the relationships between material density, strut thickness, and radiopacity, are greatly simplified in nature as is the description of the relationship between material strength, strut thickness, and stent radial strength. However, the relationships as described are sufficient to illustrate the advantages of tantalum binary alloys for use in stents.

For comparison purposes, a type 316L stainless steel stent with a strut thickness of .002 inch may be used as a baseline. Such stents have been demonstrated to have sufficient radial strength to perform adequately as a stent over a wide range of initial delivery and expanded diameters and with a variety of common stent patterns. The primary drawback of such stents is their poor radiopacity which makes real time imaging using fluoroscopy problematic. Further, stents with poor radiopacity are virtually impossible to see under fluoroscopy during follow up procedures that may occur days, months, or years after the stent has been implanted.

As used here, initial delivery diameter refers to the stent's diameter when it is crimped about an inflation balloon, while the stent's expanded diameter refers to the diameter of the stent as implanted in a vessel lumen.

Referring now to Table 1, as can be seen, pure tantalum has about twice the density of stainless steel, while having only about two thirds of the yield strength of stainless steel. Therefore, for a given stent pattern, a tantalum stent generally requires a greater strut thickness than a stainless steel stent to achieve equivalent radial strength. This factor in combination with the material's high density yields a highly radiopaque stent that is excessively bright under fluoroscopy and which obscures the image of the surrounding tissue and lumen. In addition, the greater strut thickness leads to a larger initial delivery diameter than that of stainless steel stent of the same pattern. Large initial delivery diameters or profiles are generally regarded as undesirable. Thus, a pure tantalum stent is generally less suitable for repair of a vessel lesion than a similar stainless steel stent in most applications.

However, as can be seen from Table 1, when tantalum ("Ta") is alloyed with tungsten ("W"), the strength of the binary alloy is substantially greater than that of pure tantalum. Alloys consisting of tantalum and about 2.5% by weight tungsten have a yield strength comparable to that of type 316L stainless steel. Tungsten-tantalum alloys comprising 10% by weight tungsten have a yield strength approaching twice that of type 316L stainless steel. Further, tungsten has only a slightly greater density than tantalum, thus alloying tantalum with a small percentage of tungsten, while having a

substantial effect on strength, only marginally increases the density of the binary alloy over that of pure tantalum. Since Ta-10%W alloy has greater strength than pure tantalum, while retaining a similar density, certain goals may be achieved with the binary alloy which cannot be achieved with pure tantalum. Namely, the higher strength of the binary alloy allows for the stent's strut thickness to be reduced from that of a type 316L stainless steel stent, while maintaining equivalent radial strength. Reducing the strut thickness directly reduces the radiopacity of the stent and also reduces the initial delivery diameter of the stent.

Engineering calculations have shown that a tantalum-tungsten stent with optimum radiopacity and radial strength equivalent to that of a stainless steel stent with .0002 inch thick struts may be produced from tantalum alloys comprising about 2.5% to 15% tungsten by weight. Such a stent will have a strut thickness of about 0.0016 inch. Thus, with tantalum-tungsten alloys, stents may be produced which have superior radiopacity and lower initial delivery profiles than can be achieved with stainless steel or pure tantalum.

Another binary tantalum alloy useful for producing stents is an alloy including tantalum combined with about 25%-52% by weight niobium. Niobium ("Nb") has a density of about 10 g/cm^3 which is somewhat greater than the density of stainless steel and substantially less than the density of pure tantalum. Referring again to Table 1, an alloy of tantalum comprising 40% by weight niobium has a density of about 12.1 g/cm^3 with a yield strength similar to that of type 316L stainless steel. Thus, a Ta-40%Nb stent will have a radial strength comparable to that of a stainless steel stent and a radiopacity between that of a stainless steel stent and a pure tantalum stent when all three stents have the same pattern and strut thickness.

An additional advantage of both Ta-W and Ta-Nb alloys over that of stainless steel is that these alloys form a passive oxide film primarily composed of tantalum oxide (Ta_2O_5), which is generally more durable and more corrosion resistant than the chromium-oxide film formed during the passivation of stainless steel stents. For corrosion properties, Ta-W and Ta-Nb alloys are far superior to stainless steel. For

example, tantalum- and niobium-based materials are commonly used in the chemical process industries to handle sulfuric and hydrochloric acid solutions that would rapidly attack 316L stainless steel.

Some individuals have exhibited a hypersensitivity to nickel which is a component of stainless steel. Additionally, the chromium in stainless steel, if released can behave as a toxic heavy metal. The alloys described herein contain neither of these elements.

The above described alloys may be obtained from Cabot Performance Materials, P.O. Box 1607, 144 Holly Road, Boyertown, PA 19512. The following table provides a list of the elements present in each alloy along with their precentages by weight. These are typical or average values.

Table 2

	90%Ta-2.5%W	90%Ta-10%W	60%Ta-40%Nb
Carbon	0.010	0.010	0.010
Oxygen	0.015	0.015	0.020
Nitrogen	0.010	0.010	0.010
Hydrogen	0.0015	0.0015	0.0015
Niobium	0.500	0.100	35.0-42.0
Iron	0.010	0.100	0.010
Titanium	0.010	0.010	0.010
Tungsten	2.0-3.5	9.0-11.0	0.050
Molybednum	0.020	0.020	0.020
Silicon	0.005	0.005	0.005
Nickel	0.010	0.010	0.010
Tantalum	remainder	remainder	remainder

Before describing in detail an exemplary embodiment of a strut pattern for a tantalum binary alloy stent in accordance with the present invention, it is instructive to briefly describe a typical stent implantation procedure and the vascular conditions which are typically treated with stents. Referring now to FIG. 1, a stent 10 of the present invention is shown mounted on a catheter 12 having a lumen 14 and an inflation member 16. The stent and catheter are shown inside a lumen 22 of an arterial vessel 24. The stent is shown positioned across a small amount of arterial plaque 23 adhering to the lumen of the artery. In some procedures, a stent is directly implanted without a prior procedure, such as balloon angioplasties. In other procedures, the plaque is the remainder of an arterial lesion which has been previously dilated or radially compressed against the walls of the artery or has been partially removed from the artery. Lesion dilation is typically accomplished by an angioplasty procedure, while lesion removal is typically accomplished by an atherectomy procedure. These and other procedures for the treatment of arterial lesions are well known to those skilled in the art.

With most lesion treatment procedures, the treated artery suffers a degree of trauma and in a certain percentage of cases may abruptly collapse or may slowly narrow over a period of time due to neointimal hyperplasia which is referred to as restenosis. To prevent either of these conditions, the treated artery is often fitted with a prosthetic device, such as the stent 10 of the present invention. The stent provides radial support for the treated vessel and thereby prevents collapse of the vessel 24 and further provides scaffolding to prevent plaque prolapse within the lumen. The stent may also be used to repair an arterial dissection, or an intimal flap, both of which are commonly found in the coronary arteries, peripheral arteries and other vessels. In order to perform its function, the stent must be accurately placed across the lesion site. Therefore, it is critical that the stent be sufficiently radiopaque so that the physician can visually locate the stent under fluoroscopy during the implantation procedure. However, it is equally important that the stent not be too radiopaque. If the stent is overly radiopaque, i.e., too bright, the physician's view of the lumen is compromised. This makes assessment of subsequent restenosis difficult. In cases where the balloon markers

are very close to the stent, the stent can blend in with the markers. Without precise visualization of the stent ends, accurate placement of the stent in a lesion, particularly in the case of an ostial lesion, can be compromised.

With continued reference to FIG. 1, in a typical stent placement procedure, a guiding catheter (not shown) is percutaneously introduced into the cardiovascular system of a patient through the femoral arteries by means of a conventional Seldinger technique and advanced within a patient's vascular system until the distal end of the guiding catheter is positioned at a point proximal to the lesion site. A guide wire 20 and the stent-delivery catheter 12 of the rapid exchange type are introduced through the guiding catheter with the guide wire sliding within the stent-delivery catheter. The guide wire is first advanced out of the guiding catheter into the arterial vessel 24 and is directed across the arterial lesion. The stent-delivery catheter is subsequently advanced over the previously advanced guide wire until the stent is properly positioned across the lesion.

Referring now to FIG. 2, once in position, the dilation balloon 16 is inflated to a predetermined size to radially expand the stent 10 against the inside of the artery wall and thereby implant the stent within the lumen 22 of the artery. The balloon is then deflated to a small profile so that the stent- delivery catheter may be withdrawn from the patient's vasculature and blood flow resumed through the artery.

Since the stent 10 is formed from an elongated tubular member, the rings and links of the stent are relatively flat in transverse cross-section, thus after implantation into the artery 24 as shown in FIG. 3, minimal interference with blood flow occurs. Eventually the stent becomes covered with endothelial cell growth which further minimizes blood flow interference. As should be appreciated by those skilled in the art, while the above-described procedure is typical, it is not the only method used in placing stents.

Typically, the stent 10 is laser cut from a solid tube. Thus, the stent does not possess discreet individual components. However, for the purposes of description it is beneficial to refer to the exemplary embodiment of the stent as being composed of cylindrical rings and connecting links. It is also beneficial to refer to the individual rings

as being composed of a combination of U, W, and Y shaped elements, as will be described below.

Referring now to FIGS. 4 and 5, the exemplary embodiment of the stent 10 is made up of a plurality of cylindrical rings 30 which extend circumferentially around the stent. The stent has an initial delivery diameter 32 as shown in FIG. 4, and an expanded or implanted diameter 34 as shown in FIG. 5. Each cylindrical ring 30 has a cylindrical ring proximal end 36 and a cylindrical ring distal end 38 (see also FIG. 6). Each cylindrical ring 30 defines a cylindrical plane 40 which is a plane defined by the proximal and distal ends of the ring, 36 and 38, and the circumferential extent as the cylindrical ring travels around the cylinder. Each cylindrical ring includes a cylindrical outer wall surface 42 which defines the outermost surface of the stent, and a cylindrical inner wall surface 44 which defines the innermost surface of the stent. The cylindrical plane 40 follows the cylindrical outer wall surface.

Referring now to FIG. 6, for the purpose of illustration only, the stent 10 is shown as a flat pattern so that the pattern of rings and links may be more clearly viewed. Each ring may be visualized as being formed from a plurality of W-shaped elements 46, U-shaped elements 48, and Y-shaped elements 50. Interconnecting each cylindrical ring are a plurality of links 52. Typically, each adjacent ring will be connected by at least one connecting link. In the exemplary embodiment, each ring is connected to each adjacent ring by three connecting links which are equally spaced at 120 degree intervals around the circumference of the stent. Typically, each connecting link is radially offset from the preceding and succeeding connecting links. Generally, radially offsetting the connecting links enhances uniform longitudinal flexibility of the stent, even though the links as shown are somewhat rigid.

With continuing reference to FIG. 6, the U, W, and Y shaped elements of the cylindrical rings 30 have a plurality of peaks 56 and valleys 58. Each adjacent ring 30 is radially offset from each subsequent ring such that the peaks of one ring are axially aligned with the valleys of the next adjacent ring. The connecting links 52 are positioned

such that each link is within the valley of a U-shaped ring-element 48 and connects the element to a peak of an adjacent ring.

The stent 10 may be produced by several methods including electro-discharge machining, ion milling, and chemical etching. However, the preferred method is to laser cut a thin-walled tubular member, such as a hypotube. In this procedure, a computer controlled laser cuts away portions of the hypotube following a pre-programmed template to form the desired strut pattern. Methods and equipment for laser machining small diameter tubing are known in the art.

The laser machining process leaves a thin heat effected zone around the pattern cut in the drawn tube and a resulting surface finish that is somewhat coarse and unsuitable for implantation in living tissue. To achieve the required surface finish, stents are typically descaled and electro-polished. One method of descaling involves immersing the stents in an alkaline cleaner and ultrasonically agitating the stents for a selected period of time. Another method involves bead blasting stents with fine glass beads. There are other procedures for descaling are well known to those skilled in the art.

The principles of electro-polishing are also known in the art. Typically, an item to be electro-polished is immersed in an electrolyte which comprises an aqueous acidic solution. The item to be polished is made a positive electrode (anode) and a negative electrode (cathode) is placed in close proximity to the anode. The anode and cathode are connected to a source of electric potential difference with the electrolyte completing the circuit between anode and cathode. Upon the passage of electric current through the electrolyte, metal is dissolved from the anode surface with protrusions being dissolved faster than depressions, thereby producing a smooth surface. The rate of material removal in an electro-polishing process is primarily a function of the electrolyte chosen and the current density in the electrolyte fluid.

Typically, with stainless steel stents, a final step in the electro-polishing process involves passivation of the newly polished surface. After removal from the electrolyte solution and rinsing with water, residual anions of the acid used in the

electrolyte remain in contact with the polished surface. The presence of such surface anions leads to deterioration of the newly polished surface when the residual anions come into contact with calcium and magnesium ions which are commonly found in non-deionized water (ordinary tap water). To prevent surface deterioration, newly polished stents are immersed in a passivation bath which typically consists of a solution of nitric acid, deionized water, and sodium dichromate. The passivation bath neutralizes the residual anions and leaves a protective, corrosion resistant, strongly adherent, transparent, chromium oxide coating on the newly polished surface.

An advantage of tantalum alloy stents is that alloys of tantalum form a tough corrosion resistant (tantalum oxide) coating during initial heat treatment of the alloy which renders the alloy relatively impervious to the corrosive effects of any residual anions that may be left on the stent surface after electro-polishing. Therefore, passivation is generally not required after electro-polishing. Niobium also forms a very corrosion-resistant oxide whose properties are very similar to that of tantalum. Niobium is less corrosion resistant than tantalum at elevated temperatures, but quite similar at room temperature.

Typically, suitably sized tubing for making the stent 10 will have an outside diameter of about 0.020 - 0.070 inch, with a wall thickness of about 0.003 - 0.007 inch. However, tubing size will vary depending upon the application. It is preferred that the stent be machined from seamless tubing. However, tubing formed by rolling flat, sheet stock into a cylinder with welded longitudinal edges is also suitable, as is rolled sheet stock which has been drawn through a circular die.

It will be appreciated that a new stent utilizing the heretofore unappreciated properties of tantalum-tungsten and tantalum-niobium alloys has been presented. The new stent is sufficiently radiopaque to be readily visualized using fluoroscopy procedures without the need of an additional radiopaque coating. Further, the new stent possesses strength equivalent to that of a stainless steel stent and may be configured with a smaller initial delivery profile.

As stated, fluoroscopy, utilizing x-rays, is by far the most popular imaging method used to visualize stents. This is the case both during an intervention (delivering a stent) and afterwards in a more diagnostic mode. The present invention stent also is visible under magnetic resonance imaging (MRI). The technique of MRI works completely differently from that of fluoroscopy. The present invention stent will show up in an MRI image in a fundamentally different way than under x-ray. The present invention metal stent will show up in an MRI image by the formation of imaging artifacts. The sources of the imaging artifacts for the present invention stent includes magnetic susceptibility and electrical conductivity. Any metal that has a magnetic susceptibility different from that of tissue will generate a susceptibility artifact. The magnitude of the artifact depends on how much the susceptibility differs from that of tissue. These artifacts usually are signal voids or dark spots on the image. Electrically conductive metals in an MRI scanner can also have electrical currents induced in them by the radio frequency pulses. For stents, this can lead to the stent shielding the lumen from the radio frequency excitation signal. Stents made of the present invention composition are amongst the most MRI-compatible, while the prior art stainless steel stents are the least MRI compatible.

While only the presently preferred embodiment has been described in detail, as will be apparent to those skilled in the art, modifications and improvements may be made to the device and method disclosed herein without departing from the scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED:

1. A stent for implantation within a vessel lumen of a patient, comprising:

a pattern of struts interconnected to form a structure that contacts the walls of the lumen to maintain the patency of the vessel, wherein the struts are made from a binary alloy of tantalum.

2. The stent of claim 1, wherein the binary alloy is Ta-Nb.

3. The stent of claim 2, wherein the percentage of Nb in the alloy is about 25% to about 52% by weight.

4. The stent of claim 2, wherein the percentage of Nb in the alloy is 40% by weight.

5. The stent of claim 1, wherein the binary alloy is Ta-W.

6. The stent of claim 5, wherein the percentage of W in the alloy is within the range of about 2.5% to about 15% by weight.

7. The stent of claim 5, wherein the percentage of W in the alloy is about 2.5% by weight.

8. The stent of claim 5, wherein the percentage of W in the alloy is about 10% by weight.

9. The stent of claim 1, wherein the stent has a radiopacity intermediate between that of a stainless steel stent and that of a tantalum stent when all three stents have a similar pattern and a similar strut thickness.

10. A radiopaque intravascular stent for use in a body lumen, comprising:

a plurality of cylindrical rings interconnected to form the stent, each cylindrical ring having a first delivery diameter and a second expanded diameter;

each cylindrical ring having a proximal end and a distal end and a cylindrical wall extending circumferentially between the proximal end and the distal end of the cylindrical ring; and

at least one connecting link attaching each cylindrical ring to an adjacent cylindrical ring; and

the cylindrical rings and connecting links being formed from a binary alloy of tantalum.

11. The stent of claim 10, wherein the binary tantalum alloy is Ta-Nb.

12. The stent of claim 11, wherein the percentage of Nb in the alloy is within the range of about 25% to about 52% by weight.

13. The stent of claim 11, wherein the percentage of Nb in the alloy is about 40% by weight.

14. The stent of claim 10, wherein the binary tantalum alloy is Ta-W.

15. The stent of claim 14, wherein the percentage of W in the alloy is within the range of about 2.5% to about 15%.

16. The stent of claim 14, wherein the percentage of W in the alloy is about 2.5%.

17. The stent of claim 14, wherein the percentage of W in the alloy is about 10%.

18. The stent of claim 14, wherein the stent has a radiopacity intermediate between that of a stainless steel stent and that of a tantalum stent when all three stents are of a similar pattern and of a similar strut thickness.

19. The stent of claim 10, wherein each cylindrical ring comprises a plurality of peaks and valleys.

20. The stent of claim 10, wherein the peaks of each cylindrical ring are axially aligned with the valleys of each adjacent cylindrical ring.

21. A radiopaque stent for use in a body lumen, comprising:

a plurality of cylindrical rings interconnected to form the stent, each cylindrical ring having a first delivery diameter and a second expanded diameter, wherein each cylindrical ring has a proximal end and a distal end and a cylindrical wall extending circumferentially between the proximal end and the distal end, and further

wherein the cylindrical rings are formed of a plurality of U-shaped portions, Y-shaped portions, and W-shaped portions; and

at least one connecting link attaches each cylindrical ring to an adjacent cylindrical ring, the connecting links being positioned substantially within the cylindrical walls of the cylindrical rings; and

the cylindrical rings and connecting links are formed from a binary alloy of tantalum.

22. The stent of claim 21, wherein the binary tantalum alloy is Ta-Nb.

23. The stent of claim 22, wherein the percentage of Nb in the alloy is within the range of about 25% to about 52% by weight.

24. The stent of claim 22, wherein the percentage of Nb in the alloy is about 40%.

25. The stent of claim 21, wherein the binary tantalum alloy is Ta-W.

26. The stent of claim 25, wherein the percentage of W in the alloy is within the range of about 2.5% to about 15% by weight.

27. The stent of claim 25, wherein the percentage of W in the alloy is about 2.5% by weight.

28. The stent of claim 25, wherein the percentage of W in the alloy is about 10% by weight.

29. The stent of claim 25, wherein the stent has radiopacity intermediate between that of a stainless steel stent and that of tantalum stent when all three stents are of a similar pattern and strut thickness.

30. The stent of claim 22, wherein the Y-shaped portions are formed from the combination of the U-shaped portions with the connecting links.

31. The stent of claim 22, wherein the W-shaped portions incorporate at least a portion of the connecting links.

32. A flexible intravascular stent for use in a body lumen, comprising:

a plurality of cylindrical rings interconnected to form the stent, each cylindrical ring having a first delivery diameter and a second expanded diameter;

each cylindrical ring having a proximal end and a distal end and a cylindrical wall extending circumferentially between the proximal end and the distal end of the cylindrical ring; and

means for attaching each cylindrical ring to an adjacent cylindrical ring, the means for attaching being positioned substantially within the cylindrical wall of the cylindrical ring; and

the cylindrical rings and means for attaching the rings are formed from a binary alloy of tantalum.

33. The stent of claim 32, wherein the binary tantalum alloy is Ta-Nb.

34. The stent of claim 33, wherein the percentage of Nb in the alloy is within the range of about 25% to about 52% by weight.

35. The stent of claim 32, wherein the percentage of Nb in the alloy is about 40% by weight.

36. The stent of claim 31, wherein the binary tantalum alloy is Ta-W.

37. The stent of claim 36, wherein the percentage of W in the alloy is within the range of about 2.5% to about 15%.

38. The stent of claim 36, wherein the percentage of W in the alloy is about 2.5% by weight.

39. The stent of claim 36, wherein the percentage of W in the alloy is about 10% by weight.

40. The stent of claim 36, wherein the stent has radiopacity intermediate between that of a stainless steel stent and that of tantalum stent when all three stents are of a similar pattern and strut thickness.

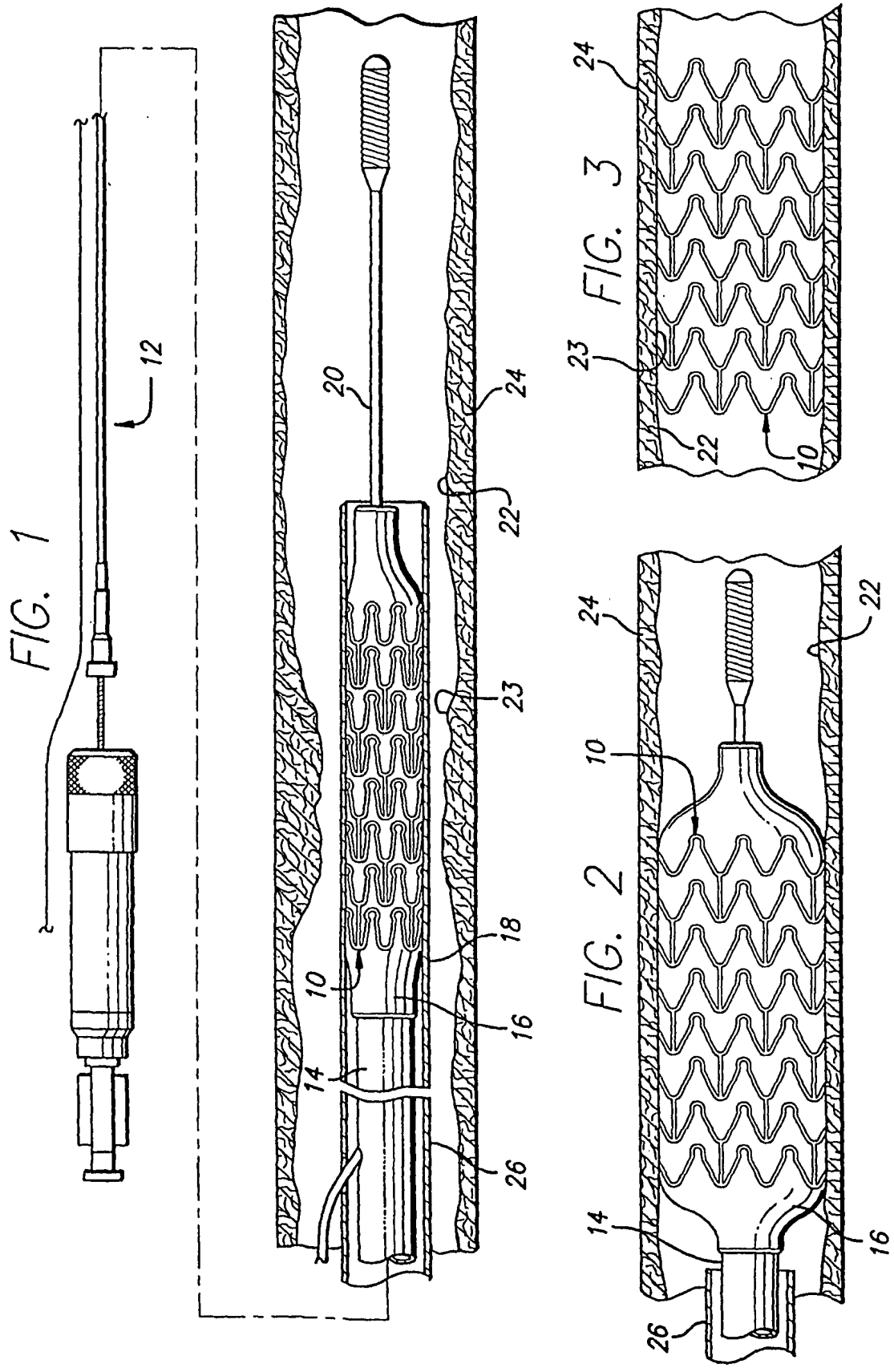
FIG. 1
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FIG. 3
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FIG. 2
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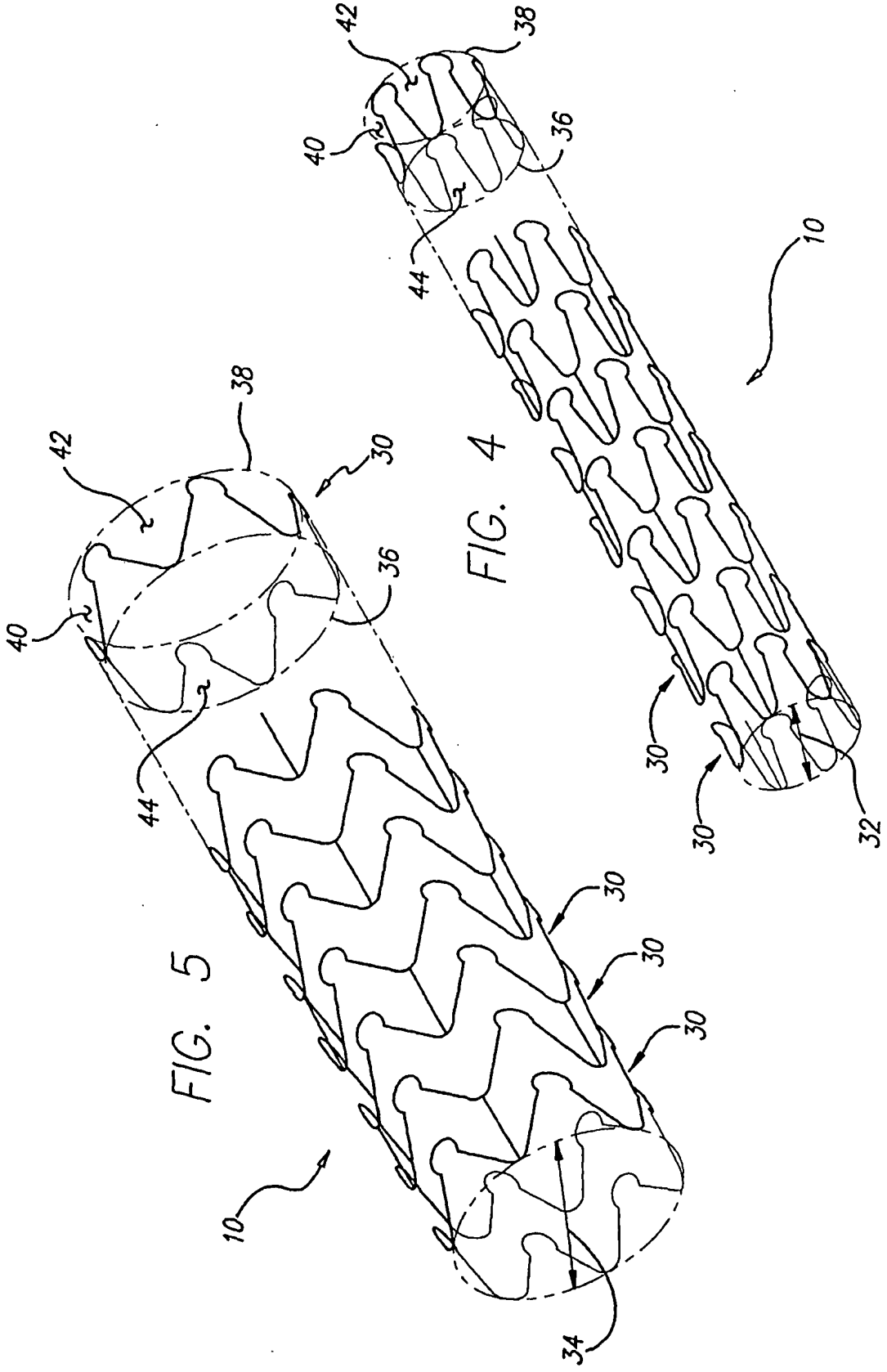
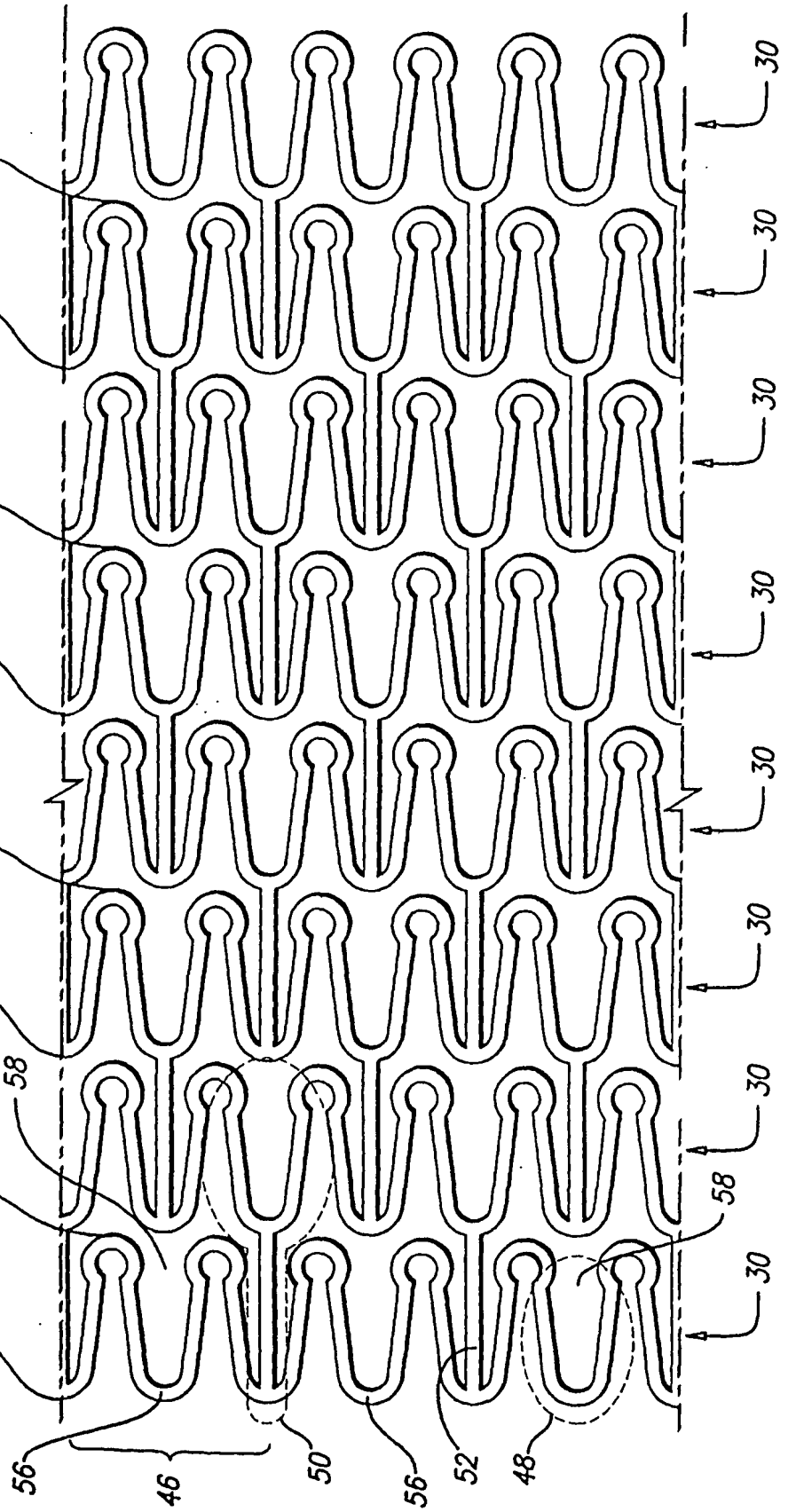


FIG. 4

FIG. 5

FIG. 6



INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/US 01/20512

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L31/02 A61F2/06 C22C27/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L A61F C22C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, PAJ, CHEM ABS Data, EPO-Internal, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CHEMICAL ABSTRACTS, vol. 108, no. 20, 16 May 1988 (1988-05-16) Columbus, Ohio, US; abstract no. 173590, SAKAGUCHI, SHIGEYA ET AL: "A titanium alloy component for bioimplants" XP002184171 abstract & JP 62 246372 A (NIPPON TUNGSTEN CO., LTD., JAPAN) 27 October 1987 (1987-10-27) ---	1
A	US 5 913 896 A (SHY JAMES M ET AL) 22 June 1999 (1999-06-22) column 6, line 1 - line 9 claims ---	1-40
A	WO 99 65537 A (MICRO SCIENCE MEDICAL AG (DE)) 23 December 1999 (1999-12-23) -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

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Date of the actual completion of the international search	Date of mailing of the international search report
28 November 2001	13/12/2001

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte nal Application No
PCT/US 01/20512

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		WO	9965537 A1	23-12-1999